



February 14, 2007

The Honorable Henry A. Waxman
Chairman, Committee on Oversight and Government Reform
United States House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

The Coalition for a Competitive Pharmaceutical Market (CCPM) applauds your leadership in introducing the landmark "Access to Life Saving Medicine Act of 2007" to bring safe, effective and more affordable biogeneric drugs to millions of Americans. We endorse this legislation and stand with you as you work with your colleagues to pass this important bill this year.


CCPM is an organization of large national employers, health plans, pharmacy benefit managers, chain pharmacies, generic drug manufacturers and others committed to improving consumer access to high quality, affordable generic medicines and promoting a vigorous, competitive prescription drug market. Experience shows that improving access to generic medicines will dramatically reduce health care costs thus expanding access to care. This is particularly true in the growing field of biopharmaceuticals. While biopharmaceuticals hold tremendous promise, their high costs – on average \$20,000 to \$200,000 annually -- too often make this promise unavailable to millions of Americans. That's why access to biogenics is so important.

Thanks to the significant scientific advances made in the biotechnology industry over the past twenty years, the science exists for the Food and Drug Administration (FDA) to establish a definitive abbreviated approval pathway that will enable them to ensure the safety and efficacy of biogenics. Your bill creates a pathway that will operate efficiently and effectively, ensure the safety and efficacy of biogenics, and produce consistent and timely reviews so that consumers can obtain the benefit of a robust competitive pharmaceutical market. We strongly support your legislation which appropriately gives FDA clear authority to use its expertise to review and, where appropriate, approve both comparable and interchangeable biogenics. We also share your goal that the FDA is best positioned to determine what testing is needed to approve comparable and interchangeable biological alternatives, and that they continue to assure the safety of all prescription drug products.

Safe and effective biogenics will bring billions of dollars of savings to consumers, state and federal governments and the healthcare community. According to a study conducted on behalf of the Pharmaceutical Care Management Association (PCMA), creating a clear pathway for approval of biogenics would save an estimated \$14 billion over ten years for the Medicare Part B program alone. This amount represents the tip of the iceberg of potential federal savings and does not include the vast majority of medications covered by Medicare, Medicaid, the Federal Employees Health Benefit Plan and other publicly financed health programs. Moreover, businesses and workers covered by private health plans would stand to save billions of dollars as well.

Passage of the "Access to Life Saving Medicine Act" should be a high priority for this Congress as it is critical to making safe and effective life improving and life saving care available and more affordable to millions of Americans. We thank you again for your leadership and look forward to working with you throughout the legislative process to increase competition in the healthcare marketplace and bring more affordable biogenics to consumers.

Sincerely,


Annette Guarisco
Chairman